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10/071,570	02/08/2002	Susanne Buser	R0134A-REG	2583

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EXAMINER

KWON, BRIAN YONG S

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/071,570

Applicant(s)

BUSER ET AL.

Examiner

Brian S Kwon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,7-19,21 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6,20 and 22-24 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Applicants Response to Election/Restrictions Requirement***

1. Applicants election, without traverse, with the Group B, claims 1-24, is acknowledged. Claim 25 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected claims.
2. In Response to the Examiner's requirement of election of species (page 3 O.A. mailed on March 25, 2003), Applicants failed to respond to the requirement. However, during a telephone conversation with Robert C. Hall on August 22, 2003 a provisional election was made to prosecute 2-(3,5-Bis-trifluoromethyl-phenyl)-N-[6-(1,1-dioxo-1 $\lambda$ 6-thiomorpholin-4-yl)-4-o-tolyl-pyridin-3yl]-N-methyl-isobutyramide as the elected species. Claims 1-3, 6, 20 and 22-24 read on the elected species. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4-5, 7-19, 21 (in addition to claim 25) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
3. Claims 1-3, 6, 20 and 22-24 are currently pending for prosecution on the merits.

### ***Compliance With Sequence Rules***

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below.

37 CFR 1,821(a) presents a definition for "nucleotide and/or amino acid sequences." This definition sets forth limits, in terms of numbers of amino acids and/or numbers of nucleotides, at

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or above which compliance with the sequence rules is required. Nucleotide and/or amino acid sequences as used in 37 CFR 1.921 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides.

This application contains sequences of four or more amino acids, for example Ac-Thr-D-Trp(FOR)-Phe-N-Mebzl (R-544); PhCO-Ala-Ala-DTrp-Phe-Dpe-Dpro-Pro-Nie-NH<sub>2</sub> (GR 94800); Tyr-D-Phe-Phe-D-His-Leu-Met-NH<sub>2</sub> (Sendide); H-Asp-Ser-Phe-Trp-beta-Ala-Leu-Met-NH<sub>2</sub> (R486) and etc..., see pages 20-24.

#### ***Information Disclosure Statement***

5. Enclosed is an initialed copy of PTO 1449 which has been considered for your records, Application No. 10/071570.

#### ***Priority***

6. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Specification***

7. The instant specification is objected to because of the following informalities: Typographical errors such as "Spendide", "NK 608" and "WIN-41,708". "Spendide", "NK 608" and "WIN-41,708" should be corrected as "Sendid", "MK 608" and "WIN-41,908" respectively.

#### ***Claim Objections***

8. Claim 24 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 recites the limitation "2-(3,5-Bis-trifluoromethyl-phenyl)-N-[6-(1,1-dioxo-1λ<sub>6</sub>-thiomorpholin-4-yl)-4-o-tolyl-pyridin-3yl]-N-methyl-isobutyramide " in claims 2 or 3. However, there is insufficient antecedent basis for this limitation in the claim. The instantly defined R<sub>4</sub> substituents in claims 2 or 3 do not embrace the claimed species in claim 20.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Fritz et al. (WO 99/07681).

Fritz teaches the use of NK-1 receptor antagonist for the treatment of benign prostatic hypertrophy (page 43, lines 23-25).

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 2-3, 6 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bos et al. (GB 2347422) in view of Fritz et al. (WO 99/07681).

Bos teaches the use of the claimed compounds represented by the general formula (I) as NK-1 receptor antagonist (abstract; pages 1-2).

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Fritz teaches the use of NK-1 receptor antagonist for the treatment of benign prostatic hypertrophy in human.

The teaching of Bos differs from the claimed invention in (i) the use of said NK-1 receptor antagonist represented by the general formula (I) for the treatment of benign prostatic hypertrophy in human; and (ii) “pKi of greater than 7” and “pKi of between 8 and 10”. To incorporate such teaching into the teaching of Bos, would have been obvious in view of Fritz who teaches the use of NK-1 receptor antagonist for the treatment of benign prostatic hypertrophy.

One having ordinary skill in the art would have expected as taught by Fritz that inappropriate stimulation of neurokinin 1 (NK-1) receptor is implicated in benign prostatic hypertrophy and NK-1 receptor antagonist is useful in relieving irritative symptoms of benign prostatic hypertrophy. Therefore, one having ordinary skill in the art would have been motivated to administer the claimed compounds having NK-1 receptor antagonist activity, with the reasonable expectation of success, to subjects suffering from irritative symptoms of benign prostatic hypertrophy such that said NK-1 receptor antagonists would effectively reduce the symptoms of benign prostatic hypertrophy.

Although Bos is silent about the claimed pKi of said NK-1 receptor antagonists represented by the general formula (I), such property or characteristic must be an expected characteristic or property of the claimed NK-1 receptor antagonists. Therefore, the references in combination make obvious the claimed invention.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-3, 6, 20 and 22-24 are provisionally rejected under the judicially created doctrine of double patenting over claims 11 of copending Application No.10/196,795. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Both the instantly claimed subject matter and the copending application are drawn to a method for treating benign prostatic hyperplasia, comprising administering NK-1 receptor antagonist, namely 2-(3,5-Bis-trifluoromethyl-phenyl)-N-[6-(1,1-dioxo-1 $\lambda$ 6-thiomorpholin-4-yl)-4-o-tolyl-pyridin-3yl]-N-methyl-isobutyramide. The scope of the present invention overlaps with the claims in copending application.

### Conclusion

13. No Claim is allowed.



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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703)308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

**ZOHREH FAY  
PRIMARY EXAMINER  
GROUP 1600**

A handwritten signature in black ink, appearing to read 'Zohreh Fay', written over the printed name.